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EXAMINER	
CHIN, BRAD Y	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 05/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,664	FISCHER ET AL.	
	Examiner	Art Unit	
	Brad Y. Chin	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 25-27 are objected to because of the following informalities: In claim 25, line 6, Applicant should change "or" to "and". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn [U.S. Patent No. 6,139,320].

Regarding claim 1, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising:

providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Fig. 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and

introducing a viscous disinfecting composition into the root canal in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal, wherein the viscous disinfecting composition is able to adhere to walls of the root canal so as to enable the disinfecting composition to disinfect the root canal (See col. 8, lines 9-39 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic

cavities; water – "slurry"; and a gelling agent – gels of glycerine or gelatine, into the root canal, where the addition of aerosiles changes the viscosity of the gels, providing for the ability of the disinfecting composition to overcome gravity, making it possible to renounce continuous supplies of the disinfecting composition, i.e. allowing the viscous disinfecting composition to adhere to the walls of the root canal so as to enable the disinfecting composition to disinfect the root canal area; See col. 4, lines 1-9 – *Hahn* teaches the use of an oscillating/vibrating device for preparing human and animal hard or soft tissue and of dental or bone replacement materials, which has a considerable shorter length than prior art ultrasonic treatment instruments and can be handled in an ergonomically favorable way like a prior art angled hand piece, thus allowing for economic use of such a tool in regions, which are difficult to access, e.g. in the intraoral treatment of hard tissue – *Hahn's* endodontic tool provides the user with control in performing dental procedures, similar to other dental instruments commonly used by dentists and oral surgeons).

Regarding claim 2, Hahn teaches the method as defined in claim 1, wherein the viscous disinfecting composition comprises sodium hypochlorite, water, and a gelling agent (See col. 8, lines 9-39 – viscous disinfecting composition comprises sodium hypochlorite, water, e.g. for the slurry, and a gelling agent, e.g. glycerine or gelatine or 1 to 10% chloro-hexidine-digluconate-gel).

Regarding claim 3, Hahn teaches the method as defined in claim 2, wherein the gelling agent comprises at least one finely divided particulate gelling agent (See col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles, making the gel more viscous and providing for the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

Regarding claim 4, Hahn teaches the method as defined in claim 3, wherein the finely divided particulate gelling agent comprises at least one of fumed silica or fumed aluminum oxide (See col. 8, lines 9-23 – in addition to the aqueous suspensions generally gel-like grain slurries of abrasive particles, e.g. granulates which at least partly contain silicates or are silanized, and/or fine grain particles. The gelling agent further comprises a thickening agent, aerosiles – a suitable fumed silica gelling agent, making the gel more viscous and allowing the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn, as described above in paragraph 2, and further in view of Clay [U.S. Patent No. 6,413,499].

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as defined above in paragraph 2, but fails to teach the method, where the gelling agent comprises at least one polymeric gelling agent or where the gelling agent comprises carboxypolymethylene.

Regarding claim 5, Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises at least one polymeric gelling agent, e.g. polyalkylene glycol, polypropylene glycol, etc. (See col. 9, lines 52 to col. 10, line 5).

Regarding claim 6, Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises carboxypolymethylene (See col. 9, lines 52 to col. 10, line 5).

Clay further teaches "whereas the liquid carrier is superior in terms of the rate and extent of penetration and absorption of the active agents, the gel carrier is superior in terms of tissue adhesion and the ability to remain where initially placed (See col. 10, lines 7-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Clay with Hahn because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. adhere to the walls of the root canal, making it possible to renounce a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, carboxypolymethylene, would serve as a thickener for the disinfecting composition.

4. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn, as described above in paragraph 2, and further in view of Lee et. al. [U.S. Patent Publication No. 2002/0192627].

Regarding claim 7-10, Hahn teaches the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 2, but fails to teach the method where the sodium hypochlorite is included in a range of about 0.01% to about 50% [claim 7]; about 0.1% to about 40% [claim 8]; about 1% to about 20% [claim 9]; and about 1% to about 20% [claim 10] by weight of the viscous disinfecting composition.

Lee et. al. teach a dental training device where the viscous disinfecting composition comprises sodium hypochlorite and other constituents in the range from about 1 to 80% by weight (See col. 6, [0057]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lee et. al. with Hahn because it would have been obvious to formulate a viscous disinfecting composition comprising sodium hypochlorite in the ranges defined in claims 7-10 with other constituents, without undue experimentation, to provide a suitable disinfectant concentration for disinfecting and sanitizing the root canal during such an endodontic procedure.

5. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn, as described above in paragraph 2, and further in view of Nance [U.S. Patent No. 6,638,064].

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 2, but fails to teach the method further comprising cleaning at

least one part of the root canal with an endodontic tool; and irrigating the root canal to remove the viscous disinfecting compound and any loosened pulp or other debris.

Regarding claims 11 and 12, Nance teaches a method for irrigating a root canal and an endodontic apparatus for use in performing root canal therapy on a tooth, which is particularly useful for irrigating a root canal possessing a non-linear central axis. Nance teaches that endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite (See col. 1, lines 27-35). Accordingly, Nance teaches a flexible endodontic tool, which comprises an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application, e.g. breaking up pulp or infected tissue in the root canal) and where the viscous disinfecting composition is introduced into the root canal by means of the endodontic file (See Figure. 1; See col. 3, lines 48-55 and col. 6, lines 9-31, respectively).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nance with Hahn's method because Hahn teaches an apparatus and method for disinfecting a root canal during an endodontic procedure, where such combination produces an endodontic tool, comprising numerous tools attached to the endodontic tool, such as tools providing the capability for cleaning at least a part of the root canal with the endodontic tool and subsequently irrigating the root canal to remove the viscous

disinfecting composition and any loosened pulp or other debris after a predetermined period of time.

6. Claims 13 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn.

Regarding claim 13, Hahn teaches the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 2, but fails to teach the method where the viscous disinfecting composition is left in the root canal for a time in a range of about 1 minute to about 1 hour.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the appropriate amount of time that the viscous disinfecting composition of Hahn should be left in the root canal during such an endodontic procedure. Use of sodium hypochlorite is a common disinfectant in endodontic procedures and thus one of ordinary skill in the art, without undue experimentation, would be able to determine that leaving the viscous disinfecting composition of Hahn in the root canal for a time ranging from about 1 minute to about 1 hour would be appropriate to disinfect the bacteria in the root canal.

Regarding claims 17-19, Hahn fails to teach the method where the viscous disinfecting composition has a pH in a range from about 8 to about 12.5 [claim 17]; from about 10 to about 12 [claim 18]; and from about 11 to about 11.5 [claim 19].

It is well known that sodium hypochlorite is typically more stable with a higher pH, e.g. a more basic pH. It is also well known that gel stability decreases with a higher pH. It is also well known that to buffer a composition's pH to be more basic, one would add a mild or strong base or other pH adjuster. Accordingly, use of such a base or pH adjuster would allow one to alter the pH levels of Hahn's viscous disinfecting composition, without undue experimentation, to

those claimed in claims 17-19, providing an appropriate pH level for use in such an endodontic procedure.

7. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn, as described above in paragraph 2, and further in view of Dickson et. al. [U.S. Patent No. 5,593,458].

Hahn teaches the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 2, but fails to teach the method where the viscous disinfecting composition has a viscosity in a range from about 500 cps to about 20,000 cps [claim 14]; about 5,000 cps to about 100,000 cps [claim 15]; and 10,000 cps to about 50,000 cps [claim 16].

Dickson teaches that a gel may be made in a variety of ways, but the gel used will typically substantially cling to a vertical surface and has a preferred viscosity range. Dickson teaches that by varying the amount of gelling or thickening agent, the viscosity resulting from the mixture in this particular invention would preferably be between 6,500 and 50,000 cps as measured in a 600 ml beaker using a Brookfield Model RD Viscometer (See Specification, col. 3, lines 24-32).

Because it is well known in the art and supported in Dickson that a gelling agent allows a user to alter the viscosity of an aqueous composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Dickson with Hahn for adding a gelling agent into a viscous disinfecting composition to produce a desired viscosity in the ranges defined in claims 14-16, without undue experimentation, providing a suitable viscous disinfectant composition that adheres to the walls of a root canal during such an endodontic procedure.

8. Claims 20 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Clay.

Regarding claim 20, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising:

providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Fig. 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and

introducing a viscous disinfecting composition into the root canal comprising sodium hypochlorite, water, and a gelling agent (See col. 8, lines 9-39 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – "slurry"; and a gelling agent – gels of glycerine or gelatine, into the root canal, where the addition of aerosiles changes the viscosity of the gels, providing for the ability of the disinfecting composition to overcome gravity, making it possible to renounce continuous supplies of the disinfecting composition, i.e. allowing the viscous disinfecting composition to adhere to the walls of the root canal so as to enable the disinfecting composition to disinfect the root canal area). Hahn fails to teach that the gelling agent comprises at least one member selected from the group consisting of fumed silica, fumed aluminum oxide, and carboxypolymethylene.

Clay teaches a method where the gelling agent, which has a viscosity such that the composition may adhere to and remain in place when applied is mixed with water, where the gelling agent comprises carboxypolymethylene (See col. 9, lines 52 to col. 10, line 5).

Clay further teaches "whereas the liquid carrier is superior in terms of the rate and extent of penetration and absorption of the active agents, the gel carrier is superior in terms of tissue adhesion and the ability to remain where initially placed (See col. 10, lines 7-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Clay with Hahn because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. adhere to the walls of the root canal, making it possible to renounce a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, carboxypolymethylene, would serve as a thickener for the disinfecting composition.

Regarding claims 22 and 23, Hahn fails to teach the method where the viscous disinfecting composition has a pH in a range from 10 to about 12 [claim 22]; and from about 11 to about 11.5 [claim 23].

It is well known that sodium hypochlorite is typically more stable with a higher pH, e.g. a more basic pH. It is also well known that gel stability decreases with a higher pH. It is also well known that to buffer a composition's pH to be more basic, one would add a mild or strong base or other pH adjuster. Accordingly, use of such a base or pH adjuster would allow one to alter the pH levels of Hahn's viscous disinfecting composition, without undue experimentation, to those claimed in claims 22-23, providing an appropriate pH level for use in such an endodontic procedure.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn and Clay, as described above in paragraph 8, and further in view of Giletto et. al. [U.S. Patent No. 6,569,353].

Hahn and Clay teach the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 8, but fails to teach the gelling agent comprises fumed silica.

Giletto et. al. teach the use of fumed silica as an ideal gelling agent, performing two primary functions of reinforcement and rheology (flow) control. Reinforcment increases the strength or viscosity of various materials. The viscosity of the gel can be easily tailored to suit a specific situation (See col. 7, lines 10-28). Giletto et. al. further explain that fumed silica is widely available and is generally used in small quantities in many products such as toothpaste, detergents, food, coatings, adhesives, concrete, cosmetics, inks, plastics, and various types of rubbers. Fumed silica acts to thicken, and suspend solids. Fumed silica gel provides good surface coverage because of its free flowing character and holds the reactive components of the formulation in-place for extended periods. Sorption of the contaminant into the gel matrix is highly effective because of the enormous surface area the fumed silica provides and because of the relatively large volume available for dissolution (See col. 7, lines 29-41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Giletto et. al. with Hahn because Hahn teaches the importance of the ability of the gelling agent to overcome gravity, e.g. adhere to the walls of the root canal, making it possible to renounce a continuous supply of the aqueous solution and evacuation thereof. Gelling agents with at least one polymeric gelling agent are common in the art. Thus, a gelling agent, which comprises at least one polymeric gelling agent, and more particularly the gelling agent, fumed silica, would serve as a thickener for the disinfecting composition.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn and Clay, as described above in paragraph 8, and further in view of Nance.

Hahn and Clay teach the method for disinfecting a root canal during an endodontic procedure as described above in paragraph 8, but fails to teach the method further comprising cleaning at least a part of the root canal with an endodontic tool; and irrigating the root canal to remove the viscous disinfecting composition and any loosened pulp or other debris.

Nance teaches a method for irrigating a root canal and an endodontic apparatus for use in performing root canal therapy on a tooth, which is particularly useful for irrigating a root canal possessing a non-linear central axis. Nance teaches that endodontics or root canal therapy is a well-known procedure where a series of very delicate flexible, rotary driven or finger-held instruments or files (endodontic tools) are used to extirpate or clean out and shape the root canal (See col. 1, lines 17-19). Because the instruments or files are incapable of removing all of the necessary tissue and debris, the endodontic procedure is followed with removal of tissues and debris trapped in the smaller lateral canals extending off the main root canal by irrigating the root canal with an injection of disinfecting composition, such as a typical disinfecting fluid in a dilute solution of sodium hypochlorite (See col. 1, lines 27-35). Accordingly, Nance teaches a flexible endodontic tool, which comprises an endodontic file (elongate shank 10 having a first end 12 and an opposite end of the shank 14, which may be angled or pointed if needed for a particular application, e.g. breaking up pulp or infected tissue in the root canal) and where the viscous disinfecting composition is introduced into the root canal by means of the endodontic file (See Figure. 1; See col. 3, lines 48-55 and col. 6, lines 9-31, respectively).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Nance with Hahn and Clay because Hahn teaches an apparatus and method for disinfecting a root canal during an endodontic procedure, where such

combination produces an endodontic tool, comprising numerous tools attached to the endodontic tool, such as tools providing the capability for cleaning at least a part of the root canal with the endodontic tool and subsequently irrigating the root canal to remove the viscous disinfecting composition and any loosened pulp or other debris after a predetermined period of time.

11. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn in view of Lee et. al. and Giletto et. al.

Regarding claim 25, Hahn teaches a method for disinfecting a root canal during an endodontic procedure, comprising:

providing access to a root canal of a tooth (dental angled hand piece 10 with ultrasonic vibration generator 16, ultrasonic deflecting head 28, and tool 36 for providing access to a root canal of a tooth – See Fig. 3; claim 65 – a method of forming a cavity in a tooth comprising the steps of obtaining and using an apparatus according to claim 1 to form the cavity); and

introducing a viscous disinfecting composition into the root canal, comprising sodium hypochlorite, water, and a gelling agent (See Specification, col. 8, lines 9-39 - introduction of viscous disinfecting composition, comprising sodium hypochlorite – for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities; water – "slurry"; and a gelling agent. The gelling agent further comprises a thickening agent, aerosiles, making the gel more viscous and allowing the ability to overcome gravity, e.g. to adhere to the walls of the root canal).

Hahn fails to teach the method where the gelling agent is at least one of fumed silica and fumed aluminum oxide and that the viscous disinfecting composition comprises sodium hypochlorite in an amount in a range of about 1% to about 20% by weight, water, and the at

least one of fumed silica and fumed aluminum oxide in an amount in a range of about 1% to about 10% by weight.

Giletto et. al. teach the use of fumed silica as an ideal gelling agent, performing two primary functions of reinforcement and rheology (flow) control. Reinforcment increases the strength or viscosity of various materials. The viscosity of the gel can be easily tailored to suit a specific situation (See col. 7, lines 10-28). Giletto et. al. further explain that fumed silica is widely available and is generally used in small quantities in many products such as toothpaste, detergents, food, coatings, adhesives, concrete, cosmetics, inks, plastics, and various types of rubbers. Fumed silica acts to thicken, and suspend solids. Fumed silica gel provides good surface coverage because of its free flowing character and holds the reactive components of the formulation in-place for extended periods. Sorption of the contaminant into the gel matrix is highly effective because of the enormous surface area the fumed silica provides and because of the relatively large volume available for dissolution (See col. 7, lines 29-41).

Lee et. al. teach a dental training device where the viscous disinfecting composition comprises sodium hypochlorite and other constituents in the range from about 1 to 80% by weight (See col. 6, [0057]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lee et. al. and Giletto et. al. with Hahn because one of ordinary skill in the art could, without undue experimentation, have formulated a viscous disinfecting composition, comprising sodium hypochlorite in an amount ranging from about 1% to about 20% (within the range of Lee's teachings), to properly disinfect and sanitize the root canal; water, to create the slurry; and the gelling agent, fumed silica – as identified above – in an amount ranging from about 1% to about 10%, to provide the appropriate viscosity for the

disinfecting composition to adhere to the walls of the root canal, for such an endodontic procedure.

Regarding claims 26 and 27, Hahn fails to teach the method where the viscous disinfecting composition has a pH in a range from 10 to about 12 [claim 26]; and from about 11 to about 11.5 [claim 27].

It is well known that sodium hypochlorite is typically more stable with a higher pH, e.g. a more basic pH. It is also well known that gel stability decreases with a higher pH. It is also well known that to buffer a composition's pH to be more basic, one would add a mild or strong base or other pH adjuster. Accordingly, use of such a base or pH adjuster would allow one to alter the pH levels of Hahn's viscous disinfecting composition, without undue experimentation, to those claimed in claims 22-23, providing an appropriate pH level for use in such an endodontic procedure.

Response to Arguments

12. Applicant's arguments filed 4 April 2005 have been fully considered but they are not persuasive.

With regard to Applicant's arguments on pages 7 and 8, the secondary references, *Clay* [U.S. Patent No. 6,413,499], *Lee* et. al. [U.S. Patent Publication No. 2002/019267], and *Nance* [U.S. Patent No. 6,638,064], used by the Examiner, are analogous prior art for the purpose of analyzing the obviousness of the subject matter at issue. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." In re Oetiker, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). See also In re Deminski, 796 F.2d 436, 230 USPQ 313 (Fed. Cir. 1986); In re Clay,

966 F.2d 656, 659, 23 USPQ2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem").

Clay is analogous prior art for the purpose of analyzing the obviousness of the subject matter at issue because *Clay* relates to the field of Applicant's endeavor, i.e. the field of dentistry, and more particularly the field of endodontics, periodontics, or oral surgery for teeth. Accordingly, one of ordinary skill in the art of dentistry, and more particularly endodontics, periodontics, and/or oral surgery for teeth, would have been aware of the characteristics of a gelling agent for reducing the viscosity of a composition, in which it is included, allowing the composition to adhere better to and remain in place when applied to a surface, such as the nasal membrane in *Clay*, and similarly a root canal surface, as described in Applicant's invention. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of *Hahn* and *Clay*, as analogous prior art related to the field of endeavor of dentistry, and more particularly to endodontics, periodontics, and oral surgery of teeth. Similarly, *Lee et. al.* and *Nance* are analogous prior art for the purpose of analyzing the obviousness of the subject matter at issue because they relate to the field of Applicant's endeavor, i.e. the field of dentistry, and more particularly the field of endodontics, periodontics, or oral surgery for teeth.

With regard to Applicant's arguments on pages 9 and 10, Examiner disagrees with Applicant's representation of *Hahn*'s device as a "jack-hammer", arguing that the device of *Hahn* fails to provide a controlled manner in which to operate the device for introducing a disinfecting composition into a root canal during an endodontic procedure.

Hahn would be understood by one of ordinary skill in the art as teaching a method for disinfecting a root canal "in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal" as recited in Applicant's claim 1. *Hahn* teaches the use of an oscillating/vibrating device for preparing human and animal hard or soft tissue and of dental or bone replacement materials, which has a considerable shorter length than prior art ultrasonic treatment instruments and can be handled in an ergonomically favorable way like a prior art angled hand piece, thus allowing for economic use of such a tool in regions, which are difficult to access, e.g. in the intraoral treatment of hard tissue (See col. 4, lines 1-9). *Hahn* further teaches use of gels for regions, which are difficult to access, e.g. gum pockets, dental interstices or endodontic cavities. The gels are useful for making tooth restorations and represent an alternative to a continuous supply of an abrasive medium. The gels may include chemically active ingredients, e.g. EDTA solution to chemically assist the removal of hard tissue or sodium hypochlorite solution for dissolving remnants of soft tissue, e.g. during the preparation of endodontic cavities, or organic acid solutions for simultaneous removal of smear layers induced by treatment and/or for micromorphological restructuration of the treated surfaces or active substances for reducing the number of germs at the treated surfaces and in the surroundings thereof (e.g. reduction of germs in gum pockets), i.e. disinfecting composition, respectively (See col. 8, lines 24-39). In other words, *Hahn* provides an endodontic tool, like many tools commonly used by dentists and oral surgeons in performing routine dental procedures in a controlled manner, and a method for the tool's use, which is designed to allow the user to provide access to a root canal of a tooth and to introduce a viscous disinfecting composition into the root canal in a controlled manner in order for the disinfecting composition to remain substantially on or within the tooth while disinfecting the root canal.

Applicant's arguments with respect to the rejection(s)of claim(s) 25 under 35 U.S.C. 103 have been fully considered and are persuasive in light of Exhibits A & B. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Giletto et. al. [U.S. Patent No. 6,569,353].

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Y. Chin whose telephone number is 571-272-2071. The examiner can normally be reached on Monday – Friday, 8:00 A.M. – 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sun (John) Kim, can be reached at 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

byc
May 18, 2005

JOHN KIM
SUPERVISORY PATENT EXAMINER